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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BALASUBRAMANIAN, VENKATARAMAN	
ART UNIT	PAPER NUMBER
1624	
MAIL DATE	DELIVERY MODE
03/13/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/689,982	COLLA ET AL.	
	Examiner	Art Unit	
	/Venkataraman Balasubramanian/	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5-7,9 and 11-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5-7,9 and 11-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/21/2007 has been entered. Claims 1, 3,5-7, 9 and 11-29 are now pending. ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5-7, 9 and 11-13 and 16-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Artico et al., WO 96/10565.

Artico et al., teaches several 6-benzyl-4-oxopyrimidines for treatment of viral infections such as HIV, which include instant compounds, composition, process of making and method of use. See page I, formula I. With the given definition of various variable groups, compounds taught by Artico include instant compounds. See entire document, especially Table 2-5 for various compounds made.

While said compound doesn't anticipate the scope of instant claims due applicants' amendment to Z excluding H as a choice, they are very closely related, being homolog that is compounds that differ in H in the reference on vs. methyl in the instant benzyl group. However, homologs and compounds that differ only by CH3 Vs H are not deemed patentably distinct absent evidence of superior or unexpected properties. See In re Wood 199 USPQ 137; In re Lohr 137 USPQ 548.

This rejection is same as made in the previous office action but now excludes claims 3, 14 and 15 . The rejection includes newly added claims. Applicants ' traversal to overcome this rejection is not persuasive. First of contrary to applicants assertion addition of a methyl is not a homolog, addition of methyl to a methyl group would result

in ethyl group, next higher homolog of methyl. Addition of methyl to CH_2 of an ethyl would result in propyl, the next homolog of ethyl. In the instant case, addition of a methyl to benzylic CH_2 would result in a higher homolog, $CH\text{-}CH_3$. The net result is insertion of a CH_2. Hence, applicants' argument that homologs are limited to linear increase in CH_2 in a chain is not persuasive. A branching is acceptable. See instant specification (page 4) where alkyl is treated as both straight and branched group.

As for applicants' argument pointing the Table 4 of the reference, applicants have not made a direct comparison of instant compound under identical condition with the prior art compound. The compounds pointed out by the applicants have substituents which are different from the prior art compound. As such the results appear to be mixed and there is no showing that a methyl for Z group contributes to such changes.

As for applicants' arguments citing *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007), all the TSM requirement is clearly met with as seen above. Furthermore, the court stated that

[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.

Such is the case with instant claims. By merely substituting a methyl on the CH_2 of the benzylic group is within the skill set of one trained in the art and applicants compound is as result of such a substitution and as court held it cannot be deemed as

patentably distinct innovation. And one trained in the art would be motivated to make such analog and expect that analog to have the same use as taught for the exemplified analog.

Contrary to applicants' urging, Takeda Chem. Indus., Ltd. V. Alphapharm Pty. Ltd., is not the point. Court held that: Prima facie case of obviousness for claimed chemical compound requires showing of structural similarity between prior art compound and claimed compound, as well as showing that prior art would have suggested making specific molecular changes necessary to achieve claimed invention; this test is consistent with legal principles prohibiting rigid application of "teaching, suggestion, or motivation" test in obviousness inquiry, since TSM test can provide helpful insight if it is not applied as rigid and mandatory formula, and since, in cases involving new chemical compounds, it remains necessary to identify some reason that would have led chemist to modify known compound, in particular manner, in order to establish prima facie obviousness of new compound.

Claimed thiazolidinedione derivatives used as antidiabetic agents cannot be found obvious over closest prior art compound, identified as "compound b," under "obvious to try" standard, since that standard is applicable if prior art contains finite number of identified, predictable solutions, whereas prior art in present case, rather than identifying predictable solutions for antidiabetic treatment, disclosed broad selection of compounds, any one of which could have been selected as "lead compound" for further investigation, and since compound b exhibited negative properties that would have directed person of ordinary skill in art away from that compound; nothing in prior art

provided motivation to narrow possibilities for lead compound to compound b, since evidence supports finding that one of ordinary skill would have chosen as starting point one of more than 90 compounds in prior art that did not disclose existence of toxicity or side effects, rather than compound with identified adverse effects.

Such is not the case in the instant. The subgenus of Artico et al., is not huge. There is guidance provided in scheme of page 12 and 14 for making compounds of the genus and hence one would be able to make the next higher homolog of the said compound. In fact, applicants had claimed both homologs and Table 2 clearly shows such analogs as active. Thus, it would have been obvious to one skilled in the art at the time of the invention was made to expect instant compounds to possess the utility taught by the applied art in view of the close structural similarity outlined above.

Hence, this rejection is proper and is maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3 and 5 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 20-23 of U.S. Patent No. 6,545,007. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter namely compound and pharmaceutical composition embraced in the instant claims are also embraced in the pharmaceutical composition claims 20-23 of the US 6,545,007. Note claim 20 includes instant compounds and the composition. Thus, it would be obvious to one trained in the art to make the pharmaceutical composition including those compounds embraced in the instant claims and expect the said composition useful as pharmaceuticals.

While said compound doesn't anticipate the scope of instant claims due applicants' amendment to Z excluding H as a choice, they are very closely related, being homolog that is compounds that differ in H in the reference on vs. methyl in the instant benzyl group. However, homologs and compounds that differ only by CH3 Vs H are not deemed patentably distinct absent evidence of superior or unexpected properties. See In re Wood 199 USPQ 137; In re Lohr 137 USPQ 548.

Thus it would have been obvious to one skilled in the art at the time of the invention was made to expect instant compounds to possess the utility taught by the applied art in view of the close structural similarity outlined above.

Claims 1, 3, 5-7, 9 and 11-29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-

15, 17-25 and 30-46 of copending Application No. 10/350,772. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter namely the pharmaceutical composition of compound of formula A and the method of use embraced in the instant claims are also embraced in the pharmaceutical composition of compound of formula A and method of use claims 1-15, 17-25 and 30-46 of copending application 10/350,772. Thus, it would be obvious to one trained in the art to make the pharmaceutical composition including those compounds embraced in the instant claims and expect the said composition useful as pharmaceuticals.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

This rejection is same as made in the previous office action. Applicants have differed addressing this rejection. As noted above, this rejection is proper and is maintained.

Claims 1, 3, 5-7, 9 and 11-29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-25 and 29 of copending Application No. 11/327,672. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter namely the pharmaceutical composition of compound of formula A and the method of use embraced in the instant claims are also embraced in the compound of formula A, pharmaceutical composition of compound of formula A and method of use claims 1-25 and 29 of copending application 11/327,672. Thus, it would be obvious to

one trained in the art to make the pharmaceutical composition including those compounds embraced in the instant claims and expect the said composition useful as pharmaceuticals.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. This rejection is same as made in the previous office action. Applicants have differed addressing this rejection. As noted above, this rejection is proper and is maintained.

Claims 1, 3, 5-7 and 9-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 and 37-80 of copending Application No. 10/833,601. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter namely the pharmaceutical composition of compound of formula A and the method of use embraced in the instant claims are also embraced in the compound of formula I, pharmaceutical composition of compound of formula I and method of use claims 1-8 and 37-80 of copending application 10/833,601. Thus, it would be obvious to one trained in the art to make the pharmaceutical composition including those compounds embraced in the instant claims and expect the said composition useful as pharmaceuticals.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. This rejection is same as made in the previous office action. Applicants have differed addressing these rejections. As noted above, these rejections are proper and are maintained.

Conclusion

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571) 272-0662. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is James O. Wilson, whose telephone number is 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAG. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-2 17-9197 (toll-free).

/Venkataraman Balasubramanian/

Primary Examiner, Art Unit 1624